MDD – Product Decision

Certificate No: 41316057-01
Date: 01 December 2020
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Med-Storm Innovation A/S
Attn: Hanne Storm
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Purpose

Assessment of the notification dated 10 November 2020 for addition of new product to your quality system certified according to LVFS 2003:11, Annex II (Swedish implementation of MDD 93/42/EEC).

Products concerned

Product category	Type/Model designation	Class	Sterile	GMDN code (not mandatory)
Pain Monitoring System				
Skin Conductance Algesimeter	Pain Sensor Ref: 1002	IIa	N	-

Conclusions/Decisions

The new device is a smaller version of the device already in the scope. Same intended use and class.

The device can be added to the scope.

Application of the CE-mark is permitted when the company's own procedures for CE-marking are fulfilled.

Additionally the REF number 1001 was added to the product list for the current device, to better identify the devices.

Follow-up assessments

At the next audit your auditor may follow-up on the implementation of the new product in the Quality system.

Appeals

Any appeal against this decision will be processed by an appeals panel at Intertek. The appeal shall be submitted to Intertek Semko AB, PO-Box 1103, SE-164 22 Kista, Sweden.

Intertek Semko AB
Notified Body MDD

Peter Nermander
Certification Authority MDD